EPA Revising Chromium Risk Study

Posted: March 1, 2012

EPA is delaying until next year its pending Integrated Risk Information System (IRIS) assessment of the risks of hexavalent chromium (Cr6) in order to craft a new version that will weigh industry-funded studies on the chemical's cancer risks that industry says warrant a weaker risk number than the agency's current draft.

In a Feb. 28 announcement on its IRIS website, the agency indicates that it will now produce a new draft assessment of the ubiquitous chemical sometime in 2013.

The new draft will consider the results from a series of studies funded by the American Chemistry Council, a chemical industry association, which are beginning to appear in peer-reviewed journals. EPA adds that the new draft will combine the assessment of Cr6 oral cancer risks with its previously separate re-assessment of Cr6's inhalation risks.

A new draft risk assessment that considers the industry studies bolsters critics' hopes that a resulting drinking water standard will not be as strict and expensive as what was expected to result from an earlier 2010 draft that did not include the new studies.

ACC's $4 million research effort seeks to rebut EPA claims that the substance is mutagenic -- meaning it causes cancer by gene mutation. Under EPA's cancer assessment guidelines, the agency is required to use a conservative linear assessment approach that assumes no safe level of exposure when substances are found to be mutagenic.

Following EPA's announcement that it will revise the study, ACC's Anne Kolton said in a March 1 statement that it is a “welcome change, given that many past reviews have fallen short of meeting scientific benchmarks. We are cautiously optimistic that this reflects that EPA is taking seriously the charge by Congress and recommendations from the National Academy of Sciences to improve the quality of assessments under the IRIS program.”

Kolton said ACC's recently released research findings on Cr6 oral exposure “increase scientific certainty on the mode of action and the uptake, distribution, and metabolism of the chemical in the body. These data should be informative to EPA as it develops its assessment and considers whether to establish a national drinking water standard for hexavalent chromium.”

EPA's inhalation risk re-assessment had been scheduled for completion in fiscal year 2013, according to a recent Government Accountability Office report. That same report stated that the oral risk assessment was to be completed in fiscal year 2012. But the oral assessment has been marked as “to be determined” on the agency's IRIS Track website for months.

According to the IRIS announcement, the agency now says, “The oral assessment will be revised to address the peer review comments and combined with the inhalation assessment, which is currently in draft development. . . . EPA anticipates that the draft assessment for hexavalent chromium (oral and inhalation) will be released for public comment and external peer review in 2013.”

EPA's announcement is a major shift from its earlier efforts to quickly finalize an analysis of risks from ingesting Cr6. Following the December 2010 release of the Environmental Working Group's results of spot-testing tap water for Cr6 in some 35 cities across the country, Administrator Lisa Jackson promised to quickly finalize the agency's assessment of Cr6 in 2011. She added that EPA was “likely” to issue a new drinking water standard as a result.

The agency released an earlier draft assessment of the chemical's risks from ingestion in September 2010, which industry and water utilities argue would result in a technically and financially impossible drinking water standard.

The draft assessment met with criticism from the peer review panel that met in May 2011. Several members of the panel encouraged EPA to wait for a series of studies underway by industry-funded consultants to pinpoint Cr6's MOA. Preliminary results from these studies presented Feb. 1 at the Toxicological Forum in Washington, DC, and again Feb. 3 with congressional staff at the Capitol, suggest Cr6 is not mutagenic. The studies' authors argue that the information should lead EPA to assess Cr6's risks with a less conservative, non-linear model.

EPA credits the reviewers' advice in its announcement that it is delaying the Cr6 assessment. “In their final report, the peer review panel urged EPA to consider the results of research that would soon be completed and peer-reviewed that could provide relevant scientific information that may inform the findings of the assessment,” according to a notice posted on EPA's website.

“EPA will review original primary research related to the health effects of hexavalent chromium that has been published since the release of the draft assessment for external peer review and will incorporate the findings as appropriate into its hexavalent chromium assessment,” EPA says.

Water Utilities Urge OMB To Allow Cr6 Monitoring In Pending SDWA Rule

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Water utilities, together with environmentalists, are urging the White House to quickly approve EPA's final rule updating the list of unregulated drinking water contaminants that utilities must monitor and to require monitoring of hexavalent chromium (Cr6) -- the widespread contaminant present in many water supplies but which EPA does not regulate as a stand-alone substance.

The call for EPA to require Cr6 monitoring marks a reversal for utilities, which had previously urged EPA to await its pending risk assessment of the metal before requiring monitoring. They have also charged that they lacked technical methods to adequately measure Cr6 levels in drinking water.

But a utility source says with the assessment recently delayed, utilities now believe that requiring monitoring as a way to gather occurrence data will help provide EPA with a more complete picture by the time its risk assessment is completed.

EPA has also addressed utility concerns about inadequate technical methods for detecting Cr6. The agency last November published a new detection method for Cr6, which appeared to resolve utilities' concerns that they lacked methods to adequately monitor for the substance while fueling speculation that the upcoming rule will require utilities to monitor for the ubiquitous contaminant.

Representatives of the environmentalist group Clean Water Action, the Association of Municipal Water Agencies (AMWA) and the American Water Works Association (AWWA) delivered the request to EPA and Office of Management and Budget (OMB) officials Feb. 23, according to OMB's website.

"It was a simple and short meeting with a pretty simple message," an environmentalist with knowledge of the meeting says. "The 90 days that's typical for interagency review is coming to a close soon, and we would like to see the rule released."

"We just went there to try to encourage OMB to try and wrap up their review and get it out the door," an AWWA source says.

OMB formally received for review on Dec. 8 the third iteration of EPA's Unregulated Contaminant Monitoring Rule (UCMR3), which is the result of a Safe Drinking Water Act mandate that requires EPA to determine

every five years a list of no more than 30 contaminants that are suspected to be in drinking water but for which no health-based regulatory standards exist.

Utilities then must monitor for these contaminants for three years, and EPA uses the data to help determine whether new drinking maximum contaminant levels (MCLs) are needed.

Regulating Total Chromium

EPA does not currently regulate Cr6 as a stand-alone contaminant but instead regulates total chromium -- which includes both Cr6 and trivalent chromium (Cr3), another form of the compound that is a necessary nutrient in small doses. But environmentalists and public health activists argue that Cr3 may mask Cr6's toxicity and are urging EPA to craft a stand-alone Cr6 standard.

EPA, however, indicates that its total chromium standard of 100 parts per billion is based on an assumption that all of the chromium is Cr6, rather than a mixture of valence states.

Pressure for a stand-alone Cr6 standard has been growing since the Environmental Working Group, in late 2010, issued a report showing the presence of Cr6 in drinking water in some 35 cities across the country. The report raised considerable concern and prompted EPA Administrator Lisa Jackson to announce that the agency would accelerate its Integrated Risk Information System (IRIS) analysis and base an updated drinking water standard on the new assessment.

But EPA recently announced that it is delaying the risk assessment to consider test data sponsored by the American Chemistry Council (ACC). The industry group argues the study results show the substance does not cause cancer in the way EPA alleges and that officials should therefore use a less-conservative method for assessing its risks.

EPA's proposed UCMR3 rule, issued last March, did not formally propose Cr6 for monitoring, but the agency asked informally in the proposal for public comments on the idea of adding the substance to the list.

Industry and utility groups said in earlier public comments that EPA should wait to monitor for Cr6 until a risk assessment of the chemical has been completed. But with that long-delayed study now scheduled for draft release in January 2013 the AWWA source says that group now favors Cr6 for inclusion in UCMR3. The alternative, the source says, would be to wait almost four years to start gathering occurrence data for Cr6.

"The risk assessment will eventually get done, and in the meantime it takes three years to do a full cycle of UCMR, and this cycle will not start until 2013. You have to have [the risk assessment] done to have a full picture, but you need the occurrence data too . . . and UCMR is the main way to generate occurrence data," the AWWA source says. -- *David LaRoss* (dlaross@iwpnews.com)